AUG 2 4 2000

K000158

**FISMA INC.,**
**3959 West 1820 South**
**Salt Lake City, Utah 84104**
**(801) 972-0500**
**(801) 972-4884 (fax)**
**Douglas Kane, Quality Engineer**
**Preparation Date: January 14, 2000**

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**510(k) Summary of Safety and Effectiveness for the:**

**Trade Name:** Veinlase, Spectrum K8

**Common Name:** Combination Nd:YAG & Frequency Doubled Nd:YAG System

**Classification Name:** Laser Instrument, Surgical, Powered 79GEX

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**Legally Marketed Predicate Devices for Substantial Equivalence:**

* Thermolase LT-100, SoftLight 1064 Nd:YAG

* ESC/Sharplan PhotoDerm HR

* Palomar Epilaser Solid State Long Pulse Ruby

**Rationale for SE:** The Veinlase and Spectrum K8 Lasers together with Delivery Devices share similar indications for use, and similar design features such as; wavelength, beam quality, and cooling type. Control systems such as interlock devices, (safety systems) and displays are constantly monitored for user intervention. Functional features such as; power for treatment, pulse rates, energy type, and spot sizes are also similar to the aforementioned devices. The predicate devices all are able to used for hair epilation.

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**Description of Submitted Device:**

The Veinlase and Spectrum K8 Laser Systems are devices to be used in the application of hair epilation. Laser light is produced by a YAG rod charged by a krypton arc lamp which is then Q-Switched to deliver a train of pulsing delivered in one pulse called Captured Pulse™. Output powers can reach up to 300 Watts of 1064 nm with the availability of extremely short millisecond pulses. The indication for use as a hair removal instrument are warranted considering the overwhelmingly positive data that has been published in the industry. Indications for use are supported by a line of collimated handpieces with spot sizes of: 200, 400, 600, 800, and 1200 microns, as well as, 2 and 4 millimeters.

**Intended Uses of the Elite Family Lasers:**

Removal of unwanted body hair.

**Technological Characteristics and Substantial Equivalence:**

The Thermolase LT-100, SoftLight Laser System uses arc lamps as the primary form of energy to optically pump a Nd:YAG Rod. The Electro-Optic Q-Switching requires the use of an articulated arm, but the output of which is still 1064 nm. The SoftLight delivers the same wavelength, as the Spectrum K8/Veinlase and as a YAG it's a better option for darker skin type patients.

The ESC/Sharplan PhotoDerm HR™ Laser System uses broad band intense pulsed light (590-1200 nm) as the source of energy for treatment. Laser System delivers a similar wavelength (infrared), similar power, and pulses of equivalent duration. The PhotoDerm HR has a flashlamp light as the energy source for treatment which is delivered through a quartz fiber.

The Palomar Epilaser Long Pulsed Ruby Laser System is a Solid State laser which delivers 694.3 nm laser light. The visible red, like the infrared, is absorbed well by the melanin within the hair follicles. The system delivers similar average power, durations and intervals. Although the wavelength is visibly different, the absorption characteristics for the end result are very similar. The treatment energy is delivered through a optical fiber as is the case with the Spectrum K8/Veinlase.

**Conclusion:**

The Spectrum K8 / Veinlase Laser Systems are substantially equivalent to other existing surgical laser systems already in commercial distribution and being used for hair removal. The Spectrum K8 / Veinlase wavelength is safer and has less side effects than the Ruby and Alexandrite systems. Darker skinned patients are more responsive to Nd:YAG laser energy than other systems. Supportive data demonstrates these claims. We feel that there is sufficient proof that the Spectrum K8 / Veinlase Laser Systems are Substantially Equivalent to the aforementioned predicate devices for the reduction and/or elimination of unwanted bodily hair.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 24 2000

Mr. Douglas A. Kane
Quality Manager
FISMA, Inc.
3959 West 1820 South
Salt Lake City, Utah 84104

Re: K000158
Trade Name: Veinlase, Spectrum K8
Regulatory Class: II
Product Code: GEX
Dated: August 8, 2000
Received: August 14, 2000

Dear Mr. Kane:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000158

Device Name: Spectrum K8 / Veinlase

Indications For Use:

The Spectrum K8 / Veinlase laser systems are indicated in the 1064 nm wavelenghth only for the removal (epilation) of unwanted body hair.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000158

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)